



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 18 1998 3376 '98 NOV 25 P2:23

Antonio C. Martinez, II., Esq.
8707 Brittany Drive
P.O. Box 2060
Wayne, New Jersey 07474-2069

Dear Mr. Martinez:

This is in response to your letter of November 13, 1998, on behalf of American Specialty Health & Wellness of San Diego, California, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that American Specialty Health & Wellness is making the following statements, among others, for the products:

Astragalus Extract

"...promote healing..."

Vitamin E Plus

Vitamin C Complex

Vitamin C Ester C

"...healing of wounds"

Daily Multi-Mineral

Daily Multiple Vitamin + Mineral

"...for healing...and resistance to illness"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, mitigate, or cure diseases, namely wound healing and general illnesses. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 235

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Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copy: Dr. Doug Metz
American Specialty Health & Wellness
8989 Rio San Diego Drive
Suite 250
San Diego, CA 92108

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-227 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:rjm:11/17/98:docname:62292.adv:disc33

ANTONIO C. MARTINEZ, II. P.C.

ATTORNEY AT LAW

GOVERNMENT AND PUBLIC AFFAIRS COUNSEL

8707 BRITTANY DRIVE

P.O. Box 2069

WAYNE, NJ 07474-2069

TEL 973 305 1235

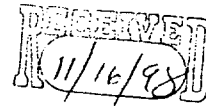
FAX 973 305 3983

62292

NEW JERSEY, NEW YORK, DISTRICT OF COLUMBIA BARS
EMAIL: TONYMARTINEZ@COMPUSERVE.COM

November 13, 1998

Office of Special Nutritionals
U.S. Food & Drug Administration
HFS-450 CFSAN
200 C St. NW
Washington DC 20204



By Federal Express Courier Service, Tracking # 7901 6502 4108

Re: Statements of Nutritional Support Filings, American Specialty Health & Wellness,
San Diego, CA

Dear Sir/Madam:

As counsel for American Specialty Health & Wellness (ASHW), enclosed please find an original and two copies of Statement of Nutritional for ninety three dietary supplement products distributed by ASHW. Should you have any questions or require any additional information, please do not hesitate to contact me.

Yours truly,

A handwritten signature in black ink, appearing to read "Antonio C. Martinez, II.". The signature is fluid and cursive, with a large, stylized "M" at the end.

Antonio C. Martinez, II. Esq.

cc: Dr. Doug Metz, ASHW



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HFS-450 Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St.SW
Washington DC 20204

Statement of Nutritional Support- DAILY MULTIPLE VITAMIN + MINERAL

Pursuant to 21 CFR Part 101.93, American Specialty Health & Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as: **DAILY MULTIPLE VITAMIN + MINERAL**

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr. Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:
"Daily Vitamin + Multiple Mineral is a combination of vitamins and minerals formulated to provide additional nutrient supplementation to the daily diet. A complete, balanced assortment of essential minerals and other nutrients is necessary for healing, growth, tissue vitality and resistance to illness."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **DAILY MULTIPLE VITAMIN + MINERAL**
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Vice President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

62292

Daily Multiple Vitamin + Minerals

Description:

Daily Multiple Vitamin + Mineral is a combination of vitamins and minerals formulated to provide additional nutrient supplementation to the daily diet. A complete, balanced assortment of essential vitamins, minerals and other nutrients is necessary for healing, growth, tissue vitality and resistance to illness.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Manganese (as amino chelate)	2mg	100%
Chromium (as nicotinate glycinate)	100mcg	83%
PABA	25mg	*

Other Ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide.

*Daily Value not established

Daily Multi-Vitamin + Minerals is free of wheat, corn, dairy, sucrose, starch, salt and yeast!

Directions for Use: Take 1 capsule 3 times per day

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication do not use it while pregnant or lactating, or provide it to a child without consulting a physician.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS™
PO BOX 509540 SAN DIEGO, CA 92150-9540

DAILY MULTI- VITAMIN + MINERALS

DIETARY SUPPLEMENT

90 CAPSULES

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 3 Capsules – Servings Per Container: 30

	Amount Per Serving	% Daily Value
Vitamin A (as beta-carotene, 8000 IU and palmitate, 4000 IU)	12,000 IU	240%
Vitamin C (as ascorbic acid)	200mg	333%
Calcium (as citrate malate)	200mg	20%
Vitamin D	200 IU	50%
Vitamin E (as d-alpha-tocopherol acetate)	100 IU	333%
Thiamin (as thiamin mononitrate)	7.5mg	500%
Riboflavin	8.5mg	500%
Niacin (as niacinamide)	25mg	125%
Vitamin B6 (as pyridoxine HCl)	10mg	500%
Folate (as folic acid)	400mcg	100%
Vitamin B12	100mcg	1667%
Biotin	400mcg	133%
Pantothenic acid	25mg	250%
Magnesium (as amino chelate)	50mg	125%
Zinc (as amino chelate, buffered)	15mg	100%
Selenium (as amino complex)	100mcg	143%
Copper (as amino chelate)	2mg	100%



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Statement of Nutritional Support- **DAILY MULTI-MINERAL**
Pursuant to 21 CFR Part 101.93, American Specialty Health & Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as: **DAILY MULTI-MINERAL**

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr.
Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:
"Daily Multiple Mineral is a unique combination of mineral nutrients formulated to provide additional nutrient supplementation to the daily diet. A complete, balanced assortment of essential minerals and other nutrients is necessary for healing, growth, tissue vitality and resistance to illness."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **DAILY MULTI-MINERAL**
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Vice President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

6229.2

Daily Multiple Mineral

Description:

Daily Multiple Mineral is a unique combination of mineral nutrients formulated to provide additional nutrient supplementation to the daily diet. A complete, balanced assortment of essential minerals and other nutrients is necessary for healing, growth, tissue vitality and resistance to illness.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions For Use: Take 1 tablet 3 times per day.

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

Chelavite® and Chelazome® are registered trademarks of Albion Laboratories, Inc.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS™
10101 509040 SAN DIEGO CA 92150 9040

DAILY MULTI-MINERAL

DIETARY SUPPLEMENT

90 TABLETS

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 3 Tablets – Servings Per Container: 30

	Amount Per Serving	% Daily Value
Potassium (as amino complex)	99mg	3%
Calcium (as amino chelate)	250mg	25%
Magnesium (as amino chelate, buffered)	100mg	25%
Zinc (as zinc Chelazome® amino chelate)	15mg	100%
Selenium (as amino complex)	100mcg	143%
Copper (as amino chelate)	2mg	100%
Manganese (as amino chelate)	3mg	150%
Chromium (as chromium Chelavite® amino chelate)	200mcg	166%
Molybdenum (as amino chelate)	50mcg	67%
Boron (as amino chelate)	500mcg	*

Other Ingredients: Gelatin, Cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide

*Daily Value not established

Daily Multi-Mineral is free of wheat, corn, soy, dairy, sucrose, starch, salt and yeast



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Statement of Nutritional Support- **VITAMIN C ESTER-C**
Pursuant to 21 CFR Part 101.93, American Specialty Health &
Wellness (ASHW) files the following Statement of Nutritional
Support for the Dietary Supplement marketed as: **VITAMIN C ESTER-C**

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr.
Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:
"Vitamin C, also known as ascorbic acid, is an antioxidant that
is required for proper tissue growth and maintenance and adrenal
gland function. Ester C has naturally bonded minerals that
help the body absorb the Vitamin C more quickly. Vitamin C
supports a healthy immune system, protects against bruising, and
assists in blood clotting, tissue formation and the healing of
wounds. Chewable C should be taken with food and chewed well, for
best absorption."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **VITAMIN C ESTER-C**
- 5) Substantiation information on file at the company office. The
corporate officer who can certify same is Dr. Doug Metz, Vice
President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

62292

Ester Vitamin C (Ascorbic Acid, Polyascorbate)

Description:

Vitamin C, also known as ascorbic acid, is an antioxidant that is required for proper tissue growth and maintenance and adrenal gland function. Ester C has naturally bonded minerals that help the body absorb the vitamin C more quickly. Vitamin C supports a healthy immune system, protects against bruising, and assists in blood clotting, tissue formation and the healing of wounds.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions For Use: Take 1 tablet per day

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not use it while pregnant or lactating provide it to a child without consulting a physician. Mega-doses can cause diarrhea and skin rashes, and long term mega-doses can cause oxalate and uric acid stone formation.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

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PO BOX 50940 • SAN DIEGO, CA 92150-9040

VITAMIN C ESTER-C®

DIETARY SUPPLEMENT

100 TABLETS

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 1 Tablet - Servings Per Container: 100

	Amount Per Serving	% Daily Value
Vitamin C (as Ester-C® calcium)	500mg	833%

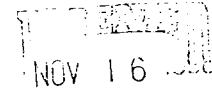
Citrus bioflavonoids
(citrus rind, std 35% bioflavonoids) 200mg

Other Ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide

*Daily Value not established

Vitamin C Ester-C is free of wheat, corn, dairy, sucrose, starch, salt and yeast

® and Ester-C™ are licensed trademarks of Inter Cal Corp. Manufactured under U.S. Patent No. 4,822,816. Other foreign patents pending.



October 30, 1998

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200 C St.SW
Washington DC 20204

Statement of Nutritional Support- **VITAMIN C COMPLEX**
Pursuant to 21 CFR Part 101.93, American Specialty Health &
Wellness (ASHW) files the following Statement of Nutritional
Support for the Dietary Supplement marketed as: **VITAMIN C COMPLEX**

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr.
Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:
"Vitamin C, also known as ascorbic acid, is an antioxidant that
is required for proper tissue growth and maintenance and adrenal
gland function. Vitamin C supports a healthy immune system,
protects against bruising, and assists in blood clotting, tissue
formation and the healing of wounds. Chewable C should be taken
with food and chewed well, for best absorption."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **VITAMIN C COMPLEX**
- 5) Substantiation information on file at the company office. The
corporate officer who can certify same is Dr. Doug Metz, Vice
President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

62292

Vitamin C Complex

Description:

Vitamin C, also known as ascorbic acid, is an antioxidant that is required for proper tissue growth and maintenance and adrenal gland function. Vitamin C supports a healthy immune system, protects against bruising, assists in blood clotting, tissue formation and the healing of wounds. Vitamin C Complex contains ascorbic acid, four forms of ascorbate and citrus bioflavonoids.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions For Use: Take 1 tablet per day.

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS™
PO BOX 509040, SAN DIEGO, CA 92150-9040

VITAMIN C COMPLEX

DIETARY SUPPLEMENT

100 TABLETS

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 1 Tablet - Servings Per Container: 100

	Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid, calcium ascorbate, magnesium ascorbate, potassium ascorbate, sodium ascorbate)	500mg	833%
Citrus bioflavonoids (citrus rind, std. 35% bioflavonoids)	100mg	*

Other Ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide

*Daily Value not established

Vitamin C Complex is free of wheat, corn, dairy, sucrose, starch salt and yeast



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200 C St.SW
Washington DC 20204

Statement of Nutritional Support- **VITAMIN E PLUS**
Pursuant to 21 CFR Part 101.93, American Specialty Health &
Wellness (ASHW) files the following Statement of Nutritional
Support for the Dietary Supplement marketed as: **VITAMIN E PLUS**

1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr.
Ste. 250, San Diego CA 92108

2) Text of Nutritional Support Statement being Made:
"Vitamin E is a fat soluble vitamin that is a powerful
antioxidant. Antioxidants protect tissue cells from damage caused
by toxic chemicals, radiation and overexposure to the sun.
Vitamin E is important in the body's cardiovascular, immune, and
endocrine system and the healing of wounds. Vitamin E works
closely with zinc and other antioxidants to strengthen many
functions of the body, including immunity."

3) Name of dietary ingredient(s): See Attached Product Label

4) Brand Name: **VITAMIN E PLUS**

5) Substantiation information on file at the company office. The
corporate officer who can certify same is Dr. Doug Metz, Vice
President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

62292-

Vitamin E Plus

Description: Vitamin E is a fat-soluble vitamin that is a powerful antioxidant. Antioxidants protect tissue cells from damage caused by toxic chemicals, radiation and overexposure to the sun. Vitamin E is important in the body's cardiovascular, immune, and endocrine system and the healing of wounds. Vitamin E works closely with zinc and other antioxidants to strengthen many functions of the body, including immunity. Vitamin E Plus also contains the mineral selenium.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions for Use: Take 1 capsule per day.

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician. Mega-dose intake of Vitamin E is reported to induce blurred vision and headache.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY HEALTH & WELLNESS™
PO BOX 507648, SAN DIEGO, CA 92158-9048

VITAMIN E PLUS

DIETARY SUPPLEMENT

90 CAPSULES

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 1 Capsule – Servings Per Container: 90

	Amount Per Serving	% Daily Value
Vitamin E (as d-alpha tocopheryl succinate)	400 IU	1,333%
Selenium (L-selenomethionine)	140mcg	200%

Other Ingredients: Gelatin, cellulose, calcium phosphate, hydroxy, stearic acid, magnesium stearate and silicon dioxide.

Vitamin E Plus is free of wheat, corn, dairy, sucrose, starch, salt and yeast.



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Statement of Nutritional Support- **ASTRAGULUS EXTRACT**
Pursuant to 21 CFR Part 101.93, American Specialty Health & Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as:
ASTRAGULUS EXTRACT

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Dr. Ste. 250, San Diego CA 92108
- 2) Text of Nutritional Support Statement being Made:
"Astragalus, also known as milk-vetch root is considered a general tonic. The root of the plant is used to support a healthy immune system, promote healing, and counteract fatigue. General tonics such as astragalus are believed to enhance the body's ability to cope and adapt to stressful conditions."
- 3) Name of dietary ingredient(s): See Attached Product Label
- 4) Brand Name: **ASTRAGULUS EXTRACT**
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Vice President.

Yours truly,

A handwritten signature in cursive script, appearing to read "Doug Metz".

Dr. Doug Metz
Vice President

62292

Astragalus Extract

Description:

Astragalus, also known as milk-vetch root, is considered a general tonic. The root of the plant is used to support a healthy immune system, promote healing and counteract fatigue. General tonics such as astragalus are believed to enhance the body's ability to cope and adapt to stressful conditions.

These statements have not been evaluated by the Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.

Directions For Use: Take 1 capsule per day.

Storage: Keep tightly closed in a cool, dry place.

Caution/Warning: As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician.

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

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PO BOX 509040, SAN DIEGO, CA 92150-9040

ASTRAGALUS EXTRACT DIETARY SUPPLEMENT

30 CAPSULES

Premium Products for Your Health & Wellness™

Supplement Facts

Serving Size: 1 Capsule – Servings Per Container: 30

	Amount Per Serving	% Daily Value
Astragalus extract (Astragalus membranaceus root, std 16% astragalosides)	450mg	*

Other Ingredients: Gelatin, cellulose, calcium phosphate hydrous, stearic acid, magnesium stearate and silicon dioxide

*Daily Value not established

Astragalus Extract is free of wheat, corn, soy, dairy, sucrose, starch, salt and yeast.